

REMARKS

Currently, claims 1, 3-13, 15-19, 21, 25 -28, 35 and 36 are pending in the application. Claims 1, 3-13, 15-19, 21, 25 -28, are withdrawn from consideration, leaving only claims 35 and 36 being actively prosecuted at this time. Additionally, new claims 37 and 38 are now added.

Both of claims 35 and 36 are now amended to independent form. Basis for the new claims is found in Claim 1 and the specification at page 10, line 30 through page 11, line 23.

I. APPLICANTS' INVENTION

The present invention relates to a removable device such as a stent-graft, intended for applications where it may be desirable to remove the device at some time following implantation. The stent-graft includes a helically-wound stent component provided with a covering of graft material having anisotropic strength properties. The graft material may also be made to include rows of perforations, lines of prescribed patterns extending through a portion of the thickness, and/or other mechanical means to aid in splitting of the graft material. The stent-graft is removable by gripping an end of the helically-wound stent component with a retrieval device and applying tension to the stent component in the direction in which it is intended to be withdrawn from the site of implantation. The use of such a retrieval device allows the stent-graft to be removed remotely, such as via a catheter inserted into the body at a different location from the implantation site. The design of the stent-graft is such that the stent component is extended axially while the adjacent portion of the graft separates between windings of the stent component. The axial extension of the stent component, with portions of the graft still joined to the stent component, allows the device to be "unraveled" (or "unwound") and removed through a catheter of diameter adequately small to be inserted into the body cavity that contained the stent-graft. It is removed atraumatically, without incurring significant trauma to the body conduit in which it had been deployed.

II. REJECTION OF CLAIMS 35 and 36 UNDER 35 USC 112, FIRST PARAGRAPH AS FAILING TO COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT.

The Examiner has concluded that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the specification was filed, had possession of the claimed invention. He states that claims 35-36 appear directed to the elected species of figure 4B and described at page 10, lines 30-36, however they depend from claim 1 which is directed to figure 4C. He adds that the specification as originally filed failed to disclose an embodiment combining the features of perforations or patterns extending through only a portion of the graft material in combination with anisotropic material.

In his "Response to Arguments" portion of the preceding Office Action wherein he disagrees with the applicants previously submission describing that the perforated graft material may be anisotropic ePTFE, the Examiner states that "...the elected species of figure 4B, clearly discloses splitting *due to* the perforation pattern."

Applicants would direct the Examiner to their specification at page 10, lines 30-36 that describes Figure 4B which states that "Figure 4 B shows a device 10 wherein the graft material 18 is *selectively weakened* by perforating the graft material in an alternative prescribed pattern 38." (Emphasis added.) It thus does not say that splitting is necessarily due *only* to the presence of the perforations.

The Examiner has concluded that, to the person of ordinary skill, to consider adding perforations to the anisotropic ePTFE "...because the perforations would have no function, and be unnecessary, if the material is designed to split apart on its own, based on the specification."

While the specification does not explicitly teach the combined use of perforations with an anisotropic material, it certainly does not teach or suggest in any way that they are exclusive to each other. Indeed, it is known to persons of ordinary skill in mechanical arts to combine splitting means such as perforations and anisotropic materials to ensure that splitting will take place along an intended line and/or with an acceptably low force. While either perforations or an anisotropic material alone may produce acceptable splitting at desired locations (as shown in Figure 2), there is no reason why both might not be used together. An example of a combination of anisotropic materials and scribed lines or

perforations would be children's balsa wood gliders wherein the components such as wings are defined by perforations that run parallel to the grain of the wood in provided sheets of thin balsa. The use of perforations in combination with an anisotropic material would further ensure that splitting occurs precisely at desired locations and/or with minimal force. The use of the combination would be entirely apparent to any person of ordinary skill in the mechanical arts.

Applicants would further point out that in their reasons for traversing the election of species ("...on the grounds that the various subspecies are defined erroneously...") as discussed in their paper of 6 April, 2005, they stated that "Thus the devices of the present invention might be provided with means for splitting as shown by either Figures 4A or 4B, while either of such devices might be made using the graft materials such as shown by Figures 4C or 4D."

Regarding claims that cover more than one embodiment, see *In re Newton*, 414 F.2d 1400, 1406, 163 USPQ 34, 39 (C.C.P.A. 1969), and *In re Smythe*, 480 F.2d 1376, 178 USPQ 279, 284 (C.C.P.A. 1973).

Regarding the written description requirement for the person of ordinary skill, please see *In re Gay*, 309 F.2d 769, 135 USPQ 311, 316 (C.C.P.A. 1962).

Arguments submitted in applicants' preceding paper of 13 November 2009 still apply.

CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

If there remain any issues that might benefit from further discussion, the Examiner is requested to telephone the undersigned practitioner; likewise, the Applicants request an interview if such issues may remain.

Respectfully Submitted,



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